

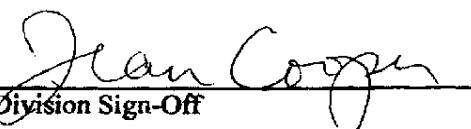
## INTENDED USE

510(k) Number: K030477

Device Name: diaDexus PLAC™ test

### Indications for Use:

The diaDexus PLAC™ test is an enzyme immunoassay for the quantitative determination of Lp-PLA2 (lipoprotein-associated phospholipase A2) in human plasma, to be used in conjunction with clinical evaluation and patient risk assessment as an aid in predicting risk for coronary heart disease.

  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K030477

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE AS  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use 

OR

Over-the-Counter Use \_\_\_\_

PM3006731403